

## **REMARKS**

### ***Claim Amendments***

Claims 1-113 are cancelled without prejudice or disclaimer. Applicant reserves the right to pursue cancelled subject matter in one or more continuation and/or divisional applications. Claims 114-193 are presented for entry and consideration. Support for the new claims can be found throughout the specification and in the claims as originally filed and, for example, at ¶¶ [096]-[106]; [118]-[120]; [167]-[170]; [236]-[240]; and Examples 4-6. Applicant respectfully requests entry of this amendment and submits that the new claims do not constitute new matter.

### ***Information Disclosure Statement***

The Office Action states that citations 7 and 8 were not considered because the year and version number of the NCBI listing was not specified. Furthermore, citation 9 was not considered because the publication year was not specified.

Applicant provides herewith a PTO/SB/08A form listing citations 7-9 with the appropriate dates. For the Examiner's convenience, Applicant also attaches herewith copies of the references. Consideration of the foregoing plus the return of a copy of the enclosed Form PTO/SB/08A with the Examiner's initials in the left column in accordance with M.P.E.P. § 609 is respectfully requested.

### ***Interview Summary Pursuant to 37 C.F.R. § 1.133(b)***

In accordance with 37 C.F.R. § 1.133(b) and M.P.E.P. § 713.04, Applicant herein provides a summary of the interview of June 19, 2007 with Primary Examiner Landsman and Examiner Hissong of the USPTO and Applicant's representatives. Applicant thanks Examiners Landsman and Hissong for agreeing to conduct the interview and appreciate the courtesies extended by the Examiners.

During the interview, the Examiners and Applicant's representatives discussed cancelling the previous pending claims and adding new claims drawn to SEQ ID NO: 2 comprising a SNP, sequences with at least 95% sequence homology comprising a SNP coupled with functional language, and compositions comprising the same. The parties discussed the enablement and written description rejections under 35 U.S.C. § 112, first paragraph, in light of these proposed claims.

The parties also discussed the art rejections under 35 U.S.C. § 102. Applicant's representatives argued that the cited references do not teach or suggest a polypeptide with any of the claimed SNPs.

Finally, the parties discussed the possibility of rejoining all of the claimed SNPs (i.e., Q102K, Q114H, K179E, V127D, or A42G) for examination in a single application. Accordingly, Applicant has presented claims drawn to polypeptides comprising any one of the following SNPs: K179E, Q102K, Q114H, V127D, or A42G and compositions comprising the same. Applicant respectfully requests that the Examiner consider rejoining and examining one or more of the SNPs in the instant application.

***Enablement Rejection under 35 U.S.C. § 112, first paragraph***

Claims 85-89 and 97-102 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabled for *an isolated polypeptide comprising a polypeptide that comprises one or more of the recited Q102K, Q114H, K179E, V127D, or A42G SNPs*, the disclosure does not reasonably provide enablement for *any other polypeptide [having] less than 100% identity to the polypeptide of SEQ ID NO: 2, or regions of SEQ ID NO: 2*. Applicant respectfully traverses this rejection.

Applicant has cancelled claims 85-89 and 97-102 rendering this rejection *moot*. Applicant, however, provides the following remarks.

The instant claims are drawn to interferon  $\alpha$ -21 (IFN $\alpha$ -21) polypeptides and compositions comprising IFN $\alpha$ -21 polypeptides that share at least 95% sequence identity with the amino acid sequence of SEQ ID NO. 2 or amino acids 24 through 189 of SEQ ID NO. 2, comprise one of the following SNPs: K179E, Q102K, Q114H, V127D, or A42G, and have at least one antiviral, antiproliferative, or immunomodulatory activity.

Initially, Applicant submits that polypeptides belonging to the IFN $\alpha$  family share a common structure and common antiviral, antiproliferative, or immunomodulatory activities. See e.g., specification at ¶¶ [007]-[011]. Applicants further submit that the specification teaches polypeptides comprising an amino acid sequence having at least 95% identity with the amino acid sequence SEQ ID NO. 2 or the amino acid sequence comprising amino acids 24 and 189 of the amino acid sequence SEQ ID NO. 2 and contain at least one of the following SNPs: A42G, Q102K, Q114H, V127D, or K179E. See e.g., specification at ¶¶ [085]-[095]; [167]-[170]. The

specification also teaches that wild-type IFN $\alpha$ -21 gene codes for an immature protein of 189 amino acids (e.g., SEQ ID NO. 2) that can be converted to a mature protein of 166 amino acids by cleavage of the signal peptide that includes the first 23 amino acids (e.g., amino acids 24 to 189 of SEQ ID NO. 2). See e.g., specification at ¶ [034] Furthermore, the specification teaches several assays for identifying polypeptides with antiviral, antiproliferative, or immunomodulatory activity. See e.g., specification at Examples 4-6. Accordingly, Applicant submits that the specification provides the requisite guidance to teach one of skill in the art how to make and use the claimed polypeptides and compositions without undue experimentation.

***Written Description Rejection under 35 U.S.C. § 112, first paragraph***

Claims 85-89 and 97-102 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. Applicant respectfully traverses this rejection.

Applicant has cancelled claims 85-89 and 97-102 rendering this rejection *moot*. Applicant, however, provides the following remarks.

Initially, Applicant submits that polypeptides belonging to the IFN $\alpha$  family share a common structure and common antiviral, antiproliferative, or immunomodulatory activities. See e.g., specification at ¶¶ [007]-[011]. Applicants further submit that the specification describes polypeptide comprising an amino acid sequence having at least 95% identity with the amino acid sequence SEQ ID NO. 2 or the amino acid sequence comprising amino acids 24 and 189 of the amino acid sequence SEQ ID NO. 2 and contain at least one of the following SNPs: A42G, Q102K, Q114H, V127D, or K179E. See e.g., specification at ¶¶ [167]-[170]. The specification also describes that wild-type IFN $\alpha$ -21 gene codes for an immature protein of 189 amino acids (e.g., SEQ ID NO. 2) that can be converted to a mature protein of 166 amino acids by cleavage of the signal peptide that includes the first 23 amino acids (e.g., amino acids 24 to 189 of SEQ ID NO. 2). See e.g., specification at ¶¶ [034]. Furthermore, the specification provides a description of IFN $\alpha$ -21 polypeptides with antiviral, antiproliferative, or immunomodulatory activity. See e.g., specification at Examples 4-6. Applicant submits that Applicant had possession of the claimed invention at the time the application was filed.

***Rejection under 35 U.S.C. § 112, second paragraph***

Claims 85-89 and 100-102 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully traverses this rejection.

Applicant has cancelled claims 85-89 and 100-102 rendering this rejection *moot*.

***Rejections under 35 U.S.C. § 102***

Claims 85-89 and 97-100 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by GB 2 079 291 (January 20, 1982) Goeddel, *et al.* ("Goeddel"). Applicant respectfully traverses this rejection.

As discussed during the interview, Applicant respectfully submits that Goeddel fails to teach or suggest a polypeptide with at least 95% sequence identity with the amino acid sequence of SEQ ID NO. 2 or amino acids 24 through 189 of SEQ ID NO. 2 and one of the following SNPs: K179E, Q102K, Q114H, V127D, or A42G. Nevertheless, Applicant has cancelled claims 1-113 rendering this rejection *moot*.

Claims 85-89 and 97-100 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,299,877 (October 9, 2001) Chen, *et al.* ("the '877 patent"). Applicant respectfully traverses this rejection.

As discussed during the interview, Applicant respectfully submits that the '877 patent fails to teach or suggest a polypeptide with at least 95% sequence identity with the amino acid sequence of SEQ ID NO. 2 or amino acids 24 through 189 of SEQ ID NO. 2 and one of the following SNPs: K179E, Q102K, Q114H, V127D, or A42G. Nevertheless, Applicant has cancelled claims 1-113 rendering this rejection *moot*.

Claims 85-89 and 97-100 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,482,613 (November 19, 2002) Goeddel, *et al.* ("the '613 patent"). Applicant respectfully traverses this rejection.

As discussed during the interview, Applicant respectfully submits that the '613 patent fails to teach or suggest a polypeptide with at least 95% sequence identity with the amino acid

sequence of SEQ ID NO. 2 or amino acids 24 through 189 of SEQ ID NO. 2 and one of the following SNPs: K179E, Q102K, Q114H, V127D, or A42G. Nevertheless, Applicant has cancelled claims 1-113 rendering this rejection *moot*.

**CONCLUSION**

Applicant respectfully submits that claims are in condition for allowance, and such disposition is earnestly solicited. Should the Examiner believe that any issues remain after consideration of this response, the Examiner encouraged to contact the Applicant's undersigned representative to discuss and resolve such issues.

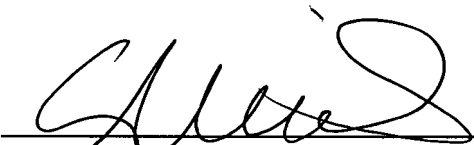
In the event that a variance exists between the amount tendered and that deemed necessary by the U.S. Patent and Trademark Office to enter and consider this Response or to maintain the present application pending, please credit or charge such variance to the undersigned's **Deposit Account No. 50-0206**.

Respectfully submitted,

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